

Safety Data Sheet

**Section 1: Identification****Product identifier**

Product Name • Polyvinyl Alcohol Ophthalmic Solution

Product Code • Core No. 067

Product Description • Dry eye therapy.

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Relieves dryness of the eye

Restrictions on use • Use in accordance with product literature.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

Section 2: Hazard Identification**UN GHS**

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Classification criteria not met

Label elements

UN GHS

Precautionary statements

Storage/Disposal • Store at 15-30°C (59-86°F)..
Keep tightly closed and store in upright position.

Other hazards

UN GHS • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzalkonium Chloride Solution	CAS:139-07-1 EINECS:205-351-5	0.01%	UN GHS: NDA
Dibasic Sodium Phosphate	CAS:7558-79-4 EINECS:231-448-7	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 0.1%	UN GHS: NDA
Monobasic Sodium Phosphate	CAS:7558-80-7 EINECS:231-449-2	< 1%	UN GHS: NDA
Polyvinyl alcohol	CAS:9002-89-5	1.4%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Not Classified

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- No specific treatment is necessary since this material is not irritating to the eye.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards

- None known - product is not flammable or combustible.

Hazardous Combustion Products

- No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures**Personal precautions, protective equipment and emergency procedures****Personal Precautions**

- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures

- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up**Containment/Clean-up Measures**

- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage**Precautions for safe handling****Handling**

- No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. Use before expiration date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection**Control parameters****Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls**Engineering Measures/Controls**

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment**Respiratory**

- No respiratory protection required during normal handling.

Eye/Face

- No eye protection is required during normal handling.

Hands

- Gloves are not required under normal handling conditions.

Skin/Body

- Not required during normal handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties**

Material Description			
Physical Form	Liquid	Appearance/Description	Not relevant
Color	Clear Colorless .	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point	Not relevant
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	= 1.009	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity**Reactivity**

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information**Information on toxicological effects**

Components		
Polyvinyl alcohol (1.4%)	9002-89-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 23854 mg/kg; <i>Behavioral:</i> Muscle weakness; Gastrointestinal: Hypermotility, diarrhea; Liver: Other changes
Benzalkonium Chloride Solution (0.01%)	139-07-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 400 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)** • Small amounts (a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.
- Chronic (Delayed)** • No data available

Carcinogenic Effects			
	CAS	IARC	NTP
Polyvinyl alcohol	9002-89-5	Group 3-Not Classifiable	Evidence of Carcinogenicity

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture****SARA Hazard Classifications**

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Benzalkonium Chloride Solution	139-07-1	Yes	Yes	Yes
Monobasic Sodium Phosphate	7558-80-7	Yes	Yes	Yes
Polyvinyl alcohol	9002-89-5	Yes	No	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Dibasic Sodium Phosphate	7558-79-4	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Uncontrolled product according to WHMIS classification criteria

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	5000 lb final RQ; 2270 kg final RQ
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Dibasic Sodium Phosphate	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride Solution	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Polyvinyl alcohol	9002-89-5	Not Listed
• Monobasic Sodium Phosphate	7558-80-7	Not Listed

Section 16 - Other Information

Last Revision Date

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